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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/006,215

10/26/2001

Kevin K. Liu

PC11053AMAG

8104

7590

07/07/2006

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EXAMINER

COLEMAN, BRENDA LIBBY

ART UNIT

PAPER NUMBER

1624

DATE MAILED: 07/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/006,215	LIU ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Brenda L. Coleman	1624	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 20 April 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-6,12,13,18,24,27 and 29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6,12,13,18,24,27 and 29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Claims 1-6, 12, 13, 18, 24, 27 and 29 are pending in the application.

This action is in response to applicants' amendment dated April 20, 2006.

Claims 1-3 and 12 have been amended and claims 19 and 20 have been canceled.

### ***Response to Arguments***

Applicant's arguments filed April 20, 2006 have been fully considered with the following effect:

1. With regards to the 35 U.S.C. § 112, first paragraph rejection of claim 27 in the last office action, applicants' state that claim 27 is directed to glucocorticoid receptor-mediated diseases or conditions does not lack enablement merely because some types of neurodegeneration may have different origins and effects. The applicants' also state that one skilled in the art could use the invention set forth in claim 27 without undue experimentation based on the details set forth in the application. However, Glezer et al. provided herein states that the role of glucocorticoids in neurodegenerative disorders associated with a robust inflammatory response is not clear. Glezer also stated that a clinical trial with glucocorticoids has been performed in patients with Alzheimer's disease, but prednisone failed to either prevent neurodegeneration or delay memory loss and dementia. Glezer concludes that corticoid therapy failed to consistently improve recovery after neuronal injury and high levels of glucocorticoids have been associated with neuronal vulnerability reveal the complexity of GC actions in the brain and that many discrepancies remain unsolved, and it is clear that both lack of glucocorticoids and exaggerated glucocorticoid levels are harmful to health. As stated in the last office

action neurodegenerative is a class of diseases and/or conditions and not a specific disease or condition as defined in the specification, i.e. neurodegeneration (for example, Alzheimer's disease and Parkinson's disease). Neurodegeneration includes more than Alzheimer's disease and Parkinson's disease such as global cerebral ischemia, amyotrophic lateral sclerosis, stroke and cystic periventricular leukomalacia. While the compounds of the present Formula (I) may have been shown to have a positive effect in the treatment of Alzheimer's disease and Parkinson's disease, this does not provide enablement for the treatment of the diseases and disorders as claimed herein. Evidence must demonstrate that the modulation of glucocorticoid and neurodegenerative diseases as a class are treatable.

Claim 27 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for reasons of record and stated above.

2. The applicants' amendments are sufficient to overcome the 35 U.S.C. § 102, anticipation rejection labeled paragraph 5 maintained in the last office action, which is hereby **withdrawn**.

3. With regards to the obviousness-type double patenting rejection of claims 1-6, 12, 13, 18-20, 24, 27 and 29 labeled paragraph 6 maintained in the last office action, the applicant's arguments have been fully considered but are not found persuasive.

The applicants stated that claim 1 has been amended so  $R_1$  is  $-C\equiv C-CH_3$  or  $-CH_2O(C_1-$

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C<sub>4</sub>)alkyl optionally substituted by -CF<sub>3</sub>. However, the claims of U.S. Patent No. 6,699,893 are such that R<sub>3</sub> is -(C<sub>2</sub>-C<sub>10</sub>)alkynyl or -CH<sub>2</sub>OR<sub>y</sub> wherein R<sub>y</sub> is -Z-CF<sub>3</sub>. More specifically the definition of R<sub>3</sub> in claim 5 is where R<sub>3</sub> is b) -C≡C-CH<sub>3</sub> and e) -CH<sub>2</sub>O(C<sub>1</sub>-C<sub>3</sub>)alkyl substituted with 0 or 1 -CF<sub>3</sub>.

Claims 1-6, 12, 13, 18, 24, 27 and 29 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of U.S. Patent No. 6,699,893, for reasons of record and stated above.

4. With regards to the obviousness-type double patenting rejection of claims 1-6, 12, 13, 18-20, 24, 27 and 29, labeled paragraph 7) maintained in the last office action, the applicants' stated that the claim amendments obviate any potential obvious-type double patent rejection if the co-pending application matures into a patent. However, recently allowed application 10/721,318 embraces the compounds and method of use of the compounds of formula (I) where R<sub>1</sub> is -C≡C-CH<sub>3</sub> or -CH<sub>2</sub>O(C<sub>1</sub>-C<sub>4</sub>)alkyl optionally substituted by -CF<sub>3</sub> and R<sub>10</sub> is -O-Z-(CO)-NR<sub>12</sub>R<sub>13</sub> or R<sub>10</sub> is -O-Z-(CO)-NH-(C<sub>0</sub>-C<sub>3</sub>)alkyl-NR<sub>12</sub>R<sub>13</sub>. For example the applicants attention is directed to claims 41 and 42 of recently allowed application 10/721,318.

Claims 1-6, 12, 13, 18, 24, 27 and 29 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-34 of copending Application No. 10/721,318, for reasons of record and stated above.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

5. The applicants' amendments are sufficient to overcome the 35 U.S.C. § 112, first paragraph rejection labeled paragraph 8 in the last office action, which is hereby **withdrawn**.

6. The applicants' amendments are sufficient to overcome the 35 U.S.C. § 112, second paragraph rejections labeled paragraph 9 in the last office action, which are hereby **withdrawn**.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda L. Coleman whose telephone number is 571-272-0665. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Brenda L. Coleman  
Primary Examiner Art Unit 1624  
July 3, 2006